510(k) Summary
for
TRILOGY Analyzer

JUL 13 2007

1. APPLICANT/SPONSOR

Drew Scientific, Inc.
4230 Shilling Way
Dallas, TX 75237

Contact Person: Roger Bourrée
Telephone: 214-210-4900

Date Prepared: June 19, 2007

2. DEVICE NAME

Proprietary Name:	TRILOGY Analyzer
Common/Usual Name:	Automated Clinical Chemistry Analyzer with Optional Ion Selective Electrode (ISE) Module
Classification Name:	Analyzer, Chemistry (Photometric, Discrete) for Clinical Use

3. PREDICATE DEVICES

- Roche Diagnostic Systems, Inc. Roche COBAS MIRA® Chemistry System (K851172)
- Medica Corp. EasyElectrolytes Analyzer (K000926)
- JAS Diagnostics, Inc. Glucose Hexokinase (Liquid) Reagent (K011900)
- JAS Diagnostics, Inc. Creatinine (Single Vial) Reagent (K003247)
- JAS Diagnostics, Inc. Urea Nitrogen (BUN) Liquid Reagent (K011596)

4. DEVICE DESCRIPTION

The TRILOGY Analyzer is a fully automated, multi-purpose analyzer used for analysis in clinical chemistry with optional ion selective electrode (ISE) module. The analyzer is intended for the in vitro measurement of various analytes in serum and urine.

The analyzer incorporates robotics, computer and communication technology to perform integrated tasks from pipetting and diluting of patient specimens, assaying specimens in Routine or STAT modes, performing spectrophotometric, and potentiometric modes simultaneously and analyzing data using multiple curve-fitting parameters.

The TRILOGY Analyzer is an open system for multiple disciplines including clinical chemistry and an optional ISE module.

5. INTENDED USE

TRILOGY is a fully automated, discrete, software-driven, multi-purpose analyzer for spectrophotometric and potentiometric in vitro determination of analytes in body fluids. It is an open system intended for clinical use in a professional setting for use with various chemistry assays that may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

TRILOGY is intended for the quantitative determination of glucose, creatinine and urea nitrogen in serum. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. Creatinine measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis. Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

TRILOGY includes an optional Ion Selective Electrodes (ISE) module for the measurement of sodium, potassium, and chloride in serum and urine. These measurements are used to monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The TRILOGY Analyzer and the predicate device, Roche COBAS MIRA® Chemistry System are fully automated instruments for analysis in clinical chemistry. The intended uses, assay types, data analysis and automation technology of the devices are similar.

The TRILOGY Analyzer with the optional Ion Selective Electrode (ISE) module and the predicate device, Medica Corp. EasyElectrolytes, are automated instruments used for analysis of analytes in serum and urine. The intended use and principle of measurement are the same.

The TRILOGY Analyzer is an open system intended for clinical use for a variety of general chemistry analyses. Three (3) representative clinical chemistry methodologies (Glucose Hexokinase Liquid Reagent, Creatinine (Single Vial) Reagent and Urea Nitrogen (BUN) Liquid Reagent), as cited above, are manufactured by JAS Diagnostics, Inc. All of these reagents are presently 510(k)-cleared under separate submissions and can be utilized without modification on the TRILOGY Analyzer.

7. PERFORMANCE TESTING

A series of nonclinical studies was conducted to evaluate the performance of the TRILOGY Analyzer and optional ISE module. These studies included method comparison, precision, linearity, interference, and limit of quantitation. The results of all studies demonstrated that the TRILOGY Analyzer performed according to its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 13 2007

Drew Scientific, Inc.
c/o Ms. Cynthia A. Sinclair, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MS 02760

Re: k070704
Trade/Device Name: Trilogy Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: Class II
Product Code: CGA, CGX, CDQ, CGZ, CEM, JGS, JJE
Dated: June 19, 2007
Received: June 20, 2007

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070704

Device Name: TRILOGY Analyzer

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Prescription Use __X__ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070704